

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION**

UNITED STATES OF AMERICA,

Plaintiff,

v.

Case No. 8:21-cv-2231-TPB-JSS

EDWARD LUBIN, M.D.

Defendant.

ORDER DENYING DEFENDANT’S MOTION TO DISMISS

This matter is before the Court on “Defendant’s, Edward Lubin, M.D., Motion to Dismiss Plaintiff’s Complaint and Incorporated Memorandum of Law in Support Thereof,” filed November 26, 2021. (Doc. 12). Plaintiff filed a response in opposition on December 13, 2021. (Doc. 17). Based on the motion, court file, and record, the Court finds as follows:

Background¹

Plaintiff United States of America (the “Government”) alleges that Defendant Edward Lubin, M.D., knowingly participated in an illegal kickback scheme orchestrated by a pharmaceutical manufacturer known as Insys Therapeutics, Inc. (“Insys”). Insys manufactured and sold Subsys, a sublingual fentanyl spray approved by the FDA for treatment of breakthrough cancer pain in patients already receiving opioid treatment for

¹ The Court accepts as true the facts alleged in the complaint for purposes of ruling on the pending motions to dismiss. *See Erickson v. Pardus*, 551 U.S. 89, 94 (2007) (“[W]hen ruling on a defendant’s motion to dismiss, a judge must accept as true all of the factual allegations contained in the complaint.”). The Court is not required to accept as true any legal conclusions couched as factual allegations. *See Papasan v. Allain*, 478 U.S. 265, 286 (1986).

underlying persistent cancer pain. Because the drug is expensive, the cost of prescriptions is often subsidized by commercial insurance or federal healthcare programs such as Medicare. Lubin was a member of Insys's "Speaker Program," pursuant to which physicians were ostensibly paid fees for delivering educational presentations regarding Subsys to other medical professionals. In fact, the program was a sham designed to disguise illegal kickbacks or bribes Insys paid the physicians in return for their prescribing high quantities of Subsys, including prescriptions that were not medically necessary. Lubin received between \$1600 and \$3700 per speaking event, for a total of almost \$160,000 over the course of his participation in the program from 2013 to 2016, and his prescriptions resulted in false claims being submitted to Medicare or TRICARE totaling millions of dollars. The complaint asserts claims against Lubin for violations of the False Claims Act ("FCA"), 31 U.S.C. § 3729(a)(1)(A) and (B), and for common law fraud. Lubin has moved to dismiss the complaint.

Legal Standard

Federal Rule of Civil Procedure 8(a) requires that a complaint contain "a short and plain statement of the claim showing the [plaintiff] is entitled to relief." Fed. R. Civ. P. 8(a). While Rule 8(a) does not demand "detailed factual allegations," it does require "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). In order to survive a motion to dismiss, factual allegations must be sufficient "to state a claim to relief that is plausible on its face." *Id.* at 570.

Where, as here, fraud is alleged, Federal Rule of Civil Procedure 9(b) requires a party alleging fraud or mistake to "state with particularity the circumstances

constituting fraud or mistake.” Fed. R. Civ. P. 9(b). As courts have explained, the purpose of Rule (9)(b) is to ensure that defendants have sufficient notice and information to formulate a defense. *See Trinity Graphic, USA, Inc. v. Tervis Tumbler Co.*, 320 F. Supp. 3d 1285, 1294 (M.D. Fla 2018). “Essentially, a plaintiff satisfies Rule 9(b) by alleging who, what, when, where, and how.” *Id.* (citing *Garfield v. NDC Health Corp.*, 466 F.3d 1255, 1262 (11th Cir. 2006)).

When deciding a Rule 12(b)(6) motion, review is generally limited to the four corners of the complaint. *Rickman v. Precisionaire, Inc.*, 902 F. Supp. 232, 233 (M.D. Fla. 1995). Furthermore, when reviewing a complaint for facial sufficiency, a court “must accept [a] [p]laintiff’s well pleaded facts as true, and construe the [c]omplaint in the light most favorable to the [p]laintiff.” *Id.* (citing *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974)). “[A] motion to dismiss should concern only the complaint’s legal sufficiency, and is not a procedure for resolving factual questions or addressing the merits of the case.” *Am. Int’l Specialty Lines Ins. Co. v. Mosaic Fertilizer, LLC*, 8:09-cv-1264-T-26TGW, 2009 WL 10671157, at *2 (M.D. Fla. Oct. 9, 2009) (Lazzara, J.).

Analysis

As set forth above, the complaint alleges that Lubin knowingly participated in a fraudulent scheme involving illegal kickbacks, medically unnecessary prescriptions, and false claims presented to Medicare and TRICARE. Rule 9(b) applies to FCA cases as well as common law fraud. *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1308-10 (11th Cir. 2002). Accordingly, the complaint is required to “state with particularity the circumstances constituting fraud” Fed. R. Civ. P. 9(b). The complaint describes the scheme and Lubin’s participation in detail, including information

on specific exemplar patients, prescriptions, and claims presented to the Government resulting from the alleged scheme. The Court finds the allegations are sufficiently particularized for purposes of Rule 9(b).

Lubin argues, however, that the complaint sets forth insufficient facts to establish that his participation in the scheme was knowing. As he puts it, “while [the] Complaint serves as a broad indictment of Insys, its employees, and its sales and marketing practices, the Complaint fails to plead facts demonstrating that Dr. Lubin himself was aware of these bad acts or knowingly participated in fraudulent activity.” Under Rule 9(b), however, a defendant’s knowledge or other state of mind may be pled generally. *See, e.g., United States ex rel. Matheny v. Medco Health Solutions, Inc.*, 671 F.3d 1217, 1224 (11th Cir. 2012) (reversing district court’s dismissal of FCA complaint on the ground that allegations that records submitted were knowingly false were insufficient). The complaint plainly does that. It alleges, for example, that Lubin acted “with actual knowledge” of the claims’ “falsity, or with deliberate ignorance or reckless disregard of the truth or falsity of the claims.”

The complaint, which covers 48 pages and includes 148 separate paragraphs, goes further, and pleads facts constituting circumstantial evidence from which the necessary state of mind could be inferred. These facts include the timing of Lubin’s receipt of compensation in relation to Subsys prescriptions, the volume of his Subsys prescriptions compared to prescriptions of other drugs, the fact the most of his Subsys prescriptions were for non-cancer patients, statements by Insys insiders that Lubin could be relied on to increase Subsys prescriptions if his compensation went up,² and the fact that some

² The complaint alleges that former Insys employees identified Lubin as a “whale,” that is, a physician who could be relied on to increase prescriptions based on payments pursuant to the

events for which Lubin received substantial compensation involved very brief visits to pharmacists at their pharmacy or never occurred at all.

Lubin also argues that the complaint's allegations that some or all of his Subsys prescriptions were not medically necessary is insufficient to show the resulting claims were "objectively false" for purposes of the FCA under *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019). *AseraCare* is factually and procedurally distinguishable. It involved claims for payment under a reimbursement scheme for hospice providers, based on physician certifications that patients admitted to hospice facilities were terminally ill. Procedurally, *AseraCare* addressed a trial court's *sua sponte* grant of summary judgment after a lengthy jury trial. Courts in this Circuit have declined to apply *AseraCare* outside of its context. *See, e.g., United States v. Cross Garden Care Ctr., LLC*, No. 8:16-cv-961-T-27AEP, 2019 WL 6493972, at *5 n.5 (M.D. Fla. Dec. 3, 2019) (explaining that *AseraCare* arose in a unique procedural posture and contained language limiting its application to Medicare claims for reimbursement for hospice services).³

The complaint alleges that some or all of the prescriptions at issue were not medically necessary and offers a number of specific facts from which that conclusion could be inferred if one draws all inferences in the Government's favor. That is

Speaker Program. An Insys sales representative involved in the scheme had her own desk in Lubin's office and reported to the sales director that "[t]he Lubin-ator is killing it!" A few weeks after this report, Lubin signed a new Speaker Program agreement that increased his payments.

³ *See also State Farm Mut. Auto. Ins. Co. v. Lewin*, 535 F. Supp. 3d 1247, 1261-62 (M.D. Fla. 2021) (noting that *AseraCare* did not address a motion to dismiss and declining to dismiss a complaint for failure to "prove that the medical opinions were objectively false at this stage"); *United States ex rel. Marsteller v. Tilton*, 556 F. Supp. 3d 1291, 1307-08 (N.D. Ala. 2021) (explaining that *AseraCare* addressed only "whether a reasonable disagreement between physicians, *without more*, was sufficient to prove falsity at summary judgment.") (quoting *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1118-19 (9th Cir. 2020)).

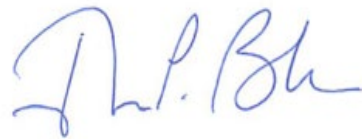
sufficient. “[A] plaintiff is not expected to actually *prove* his allegations” at the motion to dismiss stage. *Clausen*, 290 F.3d at 1313. The Court declines Lubin’s invitation to “resolv[e] factual questions or address[] the merits of the case” at this point. *Am. Int’l Specialty Lines Ins. Co.*, 2009 WL 10671157, at *2. Whether and how *AseraCare*’s “objective falsity” standard applies in this case is an issue better addressed later in the proceedings on a more complete record.

Accordingly, it is

ORDERED, ADJUDGED, and DECREED:

1. “Defendant’s, Edward Lubin, M.D., Motion to Dismiss Plaintiff’s Complaint and Incorporated Memorandum of Law in Support Thereof” (Doc. 12) is **DENIED.**
2. Defendant is directed to file his answer to the complaint on or before May 9, 2022.

DONE and ORDERED in Chambers, in Tampa, Florida, this 25th day of April, 2022.



TOM BARBER
UNITED STATES DISTRICT JUDGE